UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER
STOCK JR, GORDON J

ART UNIT	PAPER NUMBER
2877	

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/719,415	HANSEN, HEINE
	Examiner	Art Unit
	Gordon J Stock	2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *28 January 2004*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-43* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7,9-18,21-27,29-37,40 and 41* is/are rejected.

7) ☒ Claim(s) *8,19,20,28,38,39,42 and 43* is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *04 April 2001* is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Drawings and Specification

1.   The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: **claims 7 and 27** recite "after normalization of the determined spectrum with an estimate of the concentration of the dye which lacks antecedent basis; **claims 12, 17, 32, and 37** recite the term, Q_{qc}, which lacks antecedent basis; **claim 40** recites another processor and memory which lacks antecedent basis; claim 31 recites $Q_{est} = -s_2/s_1$ which lacks antecedent basis. Corrections are required.

2.   The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spectral lamp, a neon lamp of claims 40-43 and the separate memory and processor of claims 40-43 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3.   The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4.   **Claims 4, 19, 20, and 24** are objected to for the following: they lack an ending period (.).

Corrections are required.

5.   **Claims 19 and 20** are objected to for having more than one period by having ellipses. In

addition, **claim 19** does not define the term I in (N >I). Corrections are required.

6.   **Claims 11-12 and 31-32** are objected to for the following: Q_{est} and Q_{qc} both equal s_2/s_1.

Differentiation between the two terms is required.

7.   **Claims 38-39** are objected to for the following: all $A_{nod}(\lambda)$ terms should read --$A_{mod}(\lambda)$--.

Corrections are required.

8.   **Claim 42** is objected to for the following: "the spectrometer" of line 3 lacks antecedent

basis. Correction is required.

9.   **Claim 43** is objected to for the following: "the previous F_{neon}" lacks antecedent basis.

Claim Rejections - 35 USC § 112

10.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the
> subject matter which the applicant regards as his invention.

11.   **Claims 9-12, 16, 17, 29-32, 36, and 37** are rejected under 35 U.S.C. 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention.

As for **claims 9 and 29**, the terms s_1, s_2, $C_1(\lambda)$, $C_2(\lambda)$, a and b are indefinite terms, for

they are not adequately defined in relation to the first and second components of the dyes. The

terms "predetermined vectors" and "parameters" are relative terms that make the values of the s,

C, a, and b terms indefinite. **Claims 10-12 and 30-31** are rejected for depending from **claims 9**

29 respectively. In addition, **claims 12 and 32** has the term Q_{est} which is indefinite, for it is not

adequately defined. Thereby, it is a relative term that renders the value of the variable indefinite.

As for **claims 16, 17, 36 and 37**, the terms : C_{est}, C_{qc}, Q_{est} and Q_{qc} lack antecedent basis

and are not adequately defined. The terms are unspecified variables, and therefore, render their

values indefinite.

Claim Rejections - 35 USC § 103

12.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

13.   **Claims 1-4, 7, 13-16, 21-24, 27, 33-36** are rejected under 35 U.S.C. 103(a) as being

unpatentable over **Scharlack (5,828,445)** in view of **Stark et al. (5,568,400)** and **Sodickson et**

al. (5,724,268).

As for **claims 1 and 21**, Scharlack discloses a method for measuring and reporting co-

oximeter quality control results of a spectrophotometer, particularly co-oximeter, comprising

determining an absorption spectrum of a fluid quality control sample with a significant

absorbance peak with a steep flank and a reference absorption spectrum of a reference quality

control sample stored (col. 2, lines 5-20; col. 3, lines 45-67; col. 4, lines 34-55; col. 5, lines 1-25;

Figs. 1 and 4). As for the wavelength shift, an instrumental inaccuracy, it may be predetermined

by the error spectrum (col. 6, lines 1-15) since the error spectrum is the measure of the deviation

of instrumental performance from ideal. And the error spectrum is derived from a reference and

measured absorbance at each wavelength (col. 5, lines 15-25). Also Sodickson in an apparatus

for analytical concentrations that account for experimental error teaches that teaches errors such

as from wavelength shift are the difference of an observed spectrum from an ideal spectrum and

that spectra are vectors comprising intensities at wavelength ranges (col. 2, lines 40-65; col. 4,

lines 40-65; col. 5, lines 35-60). Stark also teaches multiplicative correction methods for spectra

data; whereas, the corrections depend upon normalizing, coefficient estimation (Figs. 3 and 4)

and that an error from a spectra to be removed is the difference from an ideal spectra and the

observed spectra (col. 6, lines 1-35; col. 7, lines 60-65; col. 8, lines 1-65; col. 9, lines 1-25).

Therefore, it would be obvious that the wavelength shift is determined for the error spectrum

comprises the difference between the measured and estimated spectra, an ideal spectra, at each

wavelength. The recitation of a "quality control method for a spectrophotometer" has not been

given patentable weight because it has been held that a preamble is denied the effect of a

limitation where the claim following the preamble is a self-contained description of the structure

not depending for completeness upon the introductory clause. Kropa v. Robie, 88 USPQ 478

(CCPA 1951).

As for **claims 2 and 22**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 1 and 21** above). In addition, Scharlack discloses the error spectrum is

determined from an absorption spectrum and a predetermined mathematical parameter (col. 4,

lines 35-65; col. 5, lines 1-25).

As for **claims 3-4, 23-24**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 2 and 22** above). In addition, Scharlack discloses the mathematical

parameter is a coefficient vector (col. 5, lines 25-60). As for the vector fulfilling the equation

whereas the wavelength shift equals the vector times the absorbance spectrum, Scharlack

discloses the equations 6a and 6b and 3 (col. 5, lines 11, 47, and 52). It would be obvious to one

skilled in the art at the time the invention was made that wavelength shift equals the vector times

the absorbance spectrum for the substitution of equation 3 into equation 6a gives the error

spectrum equaling a coefficient vector times the absorbance spectrum, for the error spectrum

equals $(q \cdot c_{app}) - A_{meas}$ which equals $q \cdot (q^T q)^{-1} q^T \cdot A_{meas} - A_{meas}$ which equals $(q \cdot (q^T q)^{-1} q^T - 1) A_{meas}$

which would make the error spectrum be the product of a vector times the absorbance spectrum

measured.

As for **claims 7 and 27**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 1 and 21** above). Scharlack is silent concerning normalization, but

discloses that values are made nominal are set to those values observed in normal human blood

(col. 3, lines 1-5) and well-known mathematical techniques of fitting spectra can be used (col. 5,

lines 1-10). And Stark discloses normalizing data for correcting spectra (Fig. 3). Therefore, it

will be obvious to one skilled in the art that the wavelength shifts is determined after

normalization of the determined spectrum with an estimate of the dye, for values are set to those

values in normal human blood, and normalization is a well-known mathematical technique for

correcting spectral data.

As for **claims 13 and 33**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 1 and 21** above). And Scharlack discloses a co-oximeter (col. 3, lines 45-

55).

As for **claims 14 and 34**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 13 and 33** above). And Scharlack discloses the wavelength ranges at least

500 to 640 nm (see Figs. 1-4).

As for **claims 14 and 34**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 13 and 33** above). And Scharlack discloses the wavelength ranges at least

500 to 640 nm (see Figs. 1-4).

As for **claims 15 and 35**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 13 and 33** above). And Scharlack discloses determining estimated errors in

blood parameters (col. 6, lines 1-65).

As for **claims 16 and 36**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 13 and 33** above). And Scharlack discloses determining estimated errors in

blood parameter values reported by the spectrophotometer caused by a difference between c_{est}

and c_{qc} (col. 4, lines 35-65; col. 5,1-25; col. 6, lines 1-15)

14.   **Claims 5-6, 18, 25, 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over

Scharlack (5,828,445) in view of **Stark et al. (5,568,400)** and **Sodickson et al. (5,724,268)**

further in view of **Maggard (WO 94/08225)**.

As for **claims 5-6, 25-26**, Scharlack in view of Stark and Sodickson discloses everything

as above (see **claims 4 and 24** above). In addition, Scharlack discloses the reference spectrum is

determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical

techniques of fitting are used (col. 5, lines 1-10). Maggard in a spectroscopic instrument

calibration discloses that Taylor series and linear combinations of derivatives are used in the

calibration of spectra (pages 14-17). And Stark teaches using Taylor expansions in correcting

data (col. 6, lines 25-28). Sodickson also teaches using the first derivative of the spectrum for

deriving the error-induced deviation (col. 5, lines 30-60; col. 12, lines 60-67). It would be

obvious to one skilled in the art that Taylor series and first derivatives from the reference

As for **claim 18**, Scharlack in view of Stark and Sodickson discloses everything as above (see **claim 1** above). And Scharlack discloses that a first concentration and second concentration levels are used in deriving parameters (Figs. 2 and 4). And that vectors and matrices, linear combinations of vectors, are derived (col. 5, lines 5-65). And the reference spectrum is determined on a calibrated spectrophotometer (col. 4, lines 34-50) and that known mathematical techniques of fitting are used (col. 5, lines 1-10). Maggard teaches that in a calibrating of spectra, linear combinations of derivatives are used (pages 14-17). Sodickson also teaches using the first derivative of the spectrum for deriving the error-induced deviation (col. 5, lines 30-60; col. 12, lines 60-67). Therefore, it would be obvious to one skilled in the art that the wavelength shift is derived from the first derivative, for the first derivative of a spectrum is used to derive error induced aberrations such as wavelength shift.

15.   **Claims 9-10 and 29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)** in evidence of **Stark et al. (5,568,400), Sodickson et al. (5,724,268)** and **Maggard (WO 94/08225)** in view of **Campbell et al. (EPO 0 132 399).**

As for **claims 9-10 and 29-30**, Scharlack in view of Stark and Sodickson discloses everything as above (see **claims 1 and 21** above). And Scharlack discloses "n" components (col. 4, lines 25-30). And discloses that the QC sample should mimic the samples being frequently analyzed such as blood (col. 4, lines 55-65). Campbell in cooximetry quality control reagents teaches that the quality control may contain more than one dye that mimics the spectral response of blood at a plurality of wavelengths (page 6, lines 5-10). Therefore, it would be obvious to have a quality control sample comprise more than one dye component in order to mimic blood over a plurality of wavelengths, for a co-oximeter frequently analyzes blood samples.

As for the particular parameters, Scharlack discloses similar parameters using different variables (col. 4; equations 1 and 2; col. 5; equations 3, 4, and 5). And the estimated concentration of the dye as a linear combination may be seen in the use of vectors and matrices in the estimation of absorbance spectrum and the errors in the measured concentration of blood components (col. 5, liens 5-55) and the apparent concentrations are derived (col. 6, lines 1-55). In addition, Sodickson in an apparatus for analytical concentrations that account for experimental error teaches that errors such as from wavelength shift are the difference of an observed spectrum from an ideal spectrum and that spectra are vectors comprising intensities at wavelength ranges (col. 2, lines 40-65; col. 4, lines 40-65; col. 5, lines 35-60). Maggard in a spectroscopic instrument calibration discloses that Taylor series and linear combinations of derivatives are used in the calibration of spectra (pages 14-17). And Stark teaches using Taylor expansions in correcting data (col. 6, lines 25-28).

As for c_{est} and c_{qc}, Scharlack teaches that they will be compared by the error spectrum and the relation of concentration to the absorbance spectrum (equations 4 and 5).

16.   **Claim 40** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack (5,828,445)** in view of **Stark et al. (5,568,400)** and **Sodickson et al. (5,724,268)** further in view of **Kowalski et al. (5,459,677)** and **Allen et al. (60/088816)**.

As for **claim 40**, Scharlack in view of Stark and Sodickson discloses everything as above (see **claim 21** above). In addition, Scharlack states that the spectrometer detects at least in the range 500-640 (Figs. 1-4). And discloses compensating for errors derived (col. 6, lines 1-15). The derived spectrum in memory was taken from a calibrated spectrophotometer (col. 4, lines 35-65). Scharlack is silent concerning a spectral lamp for calibrating wavelengths. However,

Kowalski in a calibration transfer for analytical instruments teaches compensating a target

instrument's response by applying a reference instruments responses (Figs. 2a, 2b, 5a, 5b). And

Allen in a method of correcting spectral response teaches using a neon source to calculate

instrument response such as shift and compensate the spectra through calibration with excitation

source's spectral response (pages 10-11; Fig. 2). Therefore, it would be obvious to one skilled in

the art at the time to have a spectral lamp such as a neon source and use its spectral response in

order to calibrate a sample's spectrum through compensating for wavelength shift due to the

system's response in order to have a more accurate spectrum for the sample tested.

17.   **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scharlack**

(5,828,445) in view of **Stark et al. (5,568,400)** and **Sodickson et al. (5,724,268)** further in view

of **Kowalski et al. (5,459,677)** and **Allen et al. (60/088816)** further in view of **Werner**

(6,103,197).

As for **claim 41**, Scharlack in view of Stark, Sodickson, Kowalski, and Allen disclose

everything as above (see **claim 40**). Scharlack is silent concerning two photodiodes for ratioing

signals. However, Werner in an apparatus for determining hemoglobin concentration teaches

having at least two photodiodes for ratioing signals for calibration purposes (col. 6, lines 10-30).

Therefore, it would be obvious to one skilled in the art to have the system comprise two

9photodiodes that have their signals ratioed in order to calibrate the system.

Response to Arguments

18.   Applicant's arguments with respect to the claims have been considered but are moot in

view of the new ground(s) of rejection.

Allowable Subject Matter

19.   **Claims 8, 19, 20, 28, 42, 43** objected to as being dependent upon a rejected base claim,

but would be allowable if rewritten in independent form including all of the limitations of the

base claim and any intervening claims and rewritten to overcome any objections as stated above.

As to **claim 8**, the prior art of record, taken alone or in combination, fails to disclose or

render obvious in a quality control method for a spectrophotometer comparing a wavelength shift

with an assigned wavelength shift, in combination with the rest of the limitations of **claim 8.**

As to **claim 19**, the prior art of record, taken alone or in combination, fails to disclose or

render obvious in a quality control method for a spectrophotometer calculating the particular set

of calibration vectors, in combination with the rest of the limitations of **claim 19.**

As to **claim 20**, the prior art of record, taken alone or in combination, fails to disclose or

render obvious in a quality control method for a spectrophotometer calculating the particular set

of calibration vectors, in combination with the rest of the limitations of **claim 20.**

As to **claim 28**, the prior art of record, taken alone or in combination, fails to disclose or

render obvious in a spectrophotometer the processor is adapted to compare a wavelength shift

with an assigned wavelength shift, in combination with the rest of the limitations of **claim 28.**

As to **claim 42**, the prior art of record, taken alone or in combination, fails to disclose or

render obvious in a spectrophotometer activation of the lamp when the temperature deviates

more than a critical temperature difference, in combination with the rest of the limitations of

claims 42-43.

20.   **Claims 38-39** are objected to but would be allowable if rewritten to overcome the

objections stated above.

As to **claim 38**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a spectrophotometer for the determination of a concentration of a component y of a sample wherein the processor is further adapted to calculating the particular concentration of the interfering component and the particular modified absorbance spectrum if the particular concentration of the interfering component is greater than a predetermined threshold value, in combination with the rest of the limitations of **claims 38-39.**

21.   **Claims 11-12, 17, 31, 32, 37** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

As to **claim 11**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a quality control method for a spectrophotometer calculating a variable Q_{est}, in combination with the rest of the limitations of **claim 11.**

As to **claim 12**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a quality control method for a spectrophotometer comparing Q_{est} with Q_{ref}, in combination with the rest of the limitations of **claim 12.**

As to **claim 17**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a quality control method for a spectrophotometer the particular step of determining estimated errors, in combination with the rest of the limitations of **claim 17.**

As to **claim 31**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a spectrophotometer the processor is adapted to calculate a variable Q_{est}, in combination with the rest of the limitations of **claim 31.**

As to **claim 32**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a spectrophotometer the processor is adapted to compare Q_{est} with Q_{ref}, in combination with the rest of the limitations of **claim 32**.

As to **claim 37**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a spectrophotometer the processor is adapted determine errors by a difference between Q_{est} and Q_{ref}, in combination with the rest of the limitations of **claim 37**.

Conclusion

22.   The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent 5,397,899 to DiFoggio et al. (compensating for instrument instabilities)

U.S. Patent 6,029,115 to Tracy et al.

U.S. Patent 6,064,899 to Fein et al.

U.S. Patent Application Publication 2001/0020123

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and

2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The

*form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30
(November 15, 1989). The CP4 Fax Machine number is:*   **(703) 872-9306**

Any inquiry concerning this communication or earlier communications from the examiner
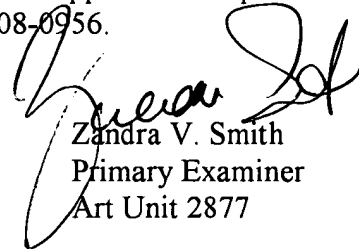should be directed to Gordon J. Stock whose telephone number is (571) 272-2431.
The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.
Any inquiry of a general nature or relating to the status of this application or proceeding should
be directed to the receptionist whose telephone number is (703) 308-0956.

gs
April 16, 2004

Zandra V. Smith
Primary Examiner
Art Unit 2877